

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0001]

Request for Nominations for Voting Members on Public Advisory Panels or Committees; Device Good Manufacturing Practice Advisory Committee and the Medical Devices Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting nominations for voting members to serve on the Device Good Manufacturing Practice Advisory Committee and device panels of the Medical Devices Advisory Committee in

the Center for Devices and Radiological Health. In accordance with the 21st Century Cures Act, this notice provides an annual opportunity for patients, representatives of patients, and sponsors of medical device submissions to provide recommendations for individuals with appropriate expertise to fill voting member positions on classification panels.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received on or before August 22, 2017, will be given first consideration for membership on the Device Good Manufacturing Practice Advisory Committee and Panels of the Medical Devices Advisory Committee. Nominations received after August 22,

2017, will be considered for nomination to the committee as later vacancies occur.

ADDRESSES: All nominations for membership should be submitted electronically by logging into the FDA Advisory Nomination Portal: <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm> or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site at <https://www.fda.gov/AdvisoryCommittees/default.htm>.

FOR FURTHER INFORMATION CONTACT: Regarding all nomination questions for membership, contact the following persons listed in table 1:

TABLE 1—COMMITTEE CONTACT

Primary contact person or designated federal officer	Committee
Sara Anderson, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G616, Silver Spring, MD 20993, 301-796-7047, email: Sara.Anderson@fda.hhs.gov .	Dental Products Panel, Hematology and Pathology Devices Panel, Orthopaedic and Rehabilitation Devices Panel.
Aden S. Asefa, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G642, Silver Spring, MD 20993, 301-796-0400, email: Aden.Asefa@fda.hhs.gov .	General Hospital and Personal Use Devices Panel, Neurological Devices Panel, Ophthalmic Devices Panel, Immunology Devices Panel, Device Good Manufacturing Practice Advisory Committee.
Shanika Craig, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G644, Silver Spring, MD 20993, 301-796-6639, email: Shanika.Craig@fda.hhs.gov .	Anesthesiology and Respiratory Therapy Devices Panel, Microbiology Devices Panel, Obstetrics and Gynecology Devices Panel, Radiological Devices Panel.
Patricio G. Garcia, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G610, Silver Spring, MD 20993, 301-796-6875, email: Patricio.Garcia@fda.hhs.gov .	Clinical Chemistry and Clinical Toxicology Panel, Gastroenterology and Urology Devices Panel, General and Plastic Surgery Devices Panel.
Pamela Scott, Office of the Center Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5572, Silver Spring, MD 20993, 301-796-5433, email: Pamelad.Scott@fda.hhs.gov .	Medical Devices Dispute Resolution Panel.
Evella F. Washington, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G640, Silver Spring, MD 20993, 301-796-6683, email: Evella.Washington@fda.hhs.gov .	Circulatory System Devices Panel, Ear, Nose and Throat Devices Panel, Molecular and Clinical Genetics Devices Panel.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members for vacancies listed in table 2:

TABLE 2—EXPERTISE NEEDED, VACANCIES, AND APPROXIMATE DATE NEEDED

Committee expertise needed	Upcoming vacancies	Approximate date needed
<i>Device Good Manufacturing Practice Advisory Committee</i> —Experts needed to provide cross-cutting scientific or clinical expertise concerning the particular issue in dispute. Vacancies include a public representative and a government representative.	5	Immediately: Health Professional (2). June 1, 2017: Government Representatives (2) and General Public Representative (1).
<i>Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee</i> —Anesthesiologists, pulmonary medicine specialists, or other experts who have specialized interests in ventilator support, pharmacology, physiology, or the effects and complications of anesthesia.	3	December 1, 2017.

TABLE 2—EXPERTISE NEEDED, VACANCIES, AND APPROXIMATE DATE NEEDED—Continued

Committee expertise needed	Upcoming vacancies	Approximate date needed
<i>Circulatory System Devices Panel of the Medical Devices Advisory Committee</i> —Interventional cardiologists, electrophysiologists, invasive (vascular) radiologists, vascular and cardiothoracic surgeons, and cardiologists with special interest in congestive heart failure.	1	July 1, 2017.
<i>Clinical Chemistry and Clinical Toxicology Panel of the Medical Devices Advisory Committee</i> —Doctors of medicine or philosophy with experience in clinical chemistry (e.g., cardiac markers), clinical toxicology, clinical pathology, clinical laboratory medicine, and endocrinology.	2	Immediately.
<i>Dental Products Panel of the Medical Devices Advisory Committee</i> —Dentists, engineers, and scientists who have expertise in the areas of dental implants, dental materials, periodontology, tissue engineering, and dental anatomy.	3	November 1, 2017.
<i>Ear, Nose and Throat Devices Panel of the Medical Devices Advisory Committee</i> —Otologists, neurologists, and audiologists.	1	Immediately.
<i>Gastroenterology and Urology, Devices Panel of the Medical Devices Advisory Committee</i> —Gastroenterologists, urologists, and nephrologists.	3	November 1, 2017.
<i>General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee</i> —Surgeons (general, plastic, reconstructive, pediatric, thoracic, abdominal, pelvic, and endoscopic); dermatologists; experts in biomaterials, lasers, wound healing, and quality of life; and biostatisticians.	1	Immediately.
<i>General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee</i> —Internists, pediatricians, neonatologists, endocrinologists, gerontologists, nurses, biomedical engineers or microbiologists/infection control practitioners or experts.	3	November 1, 2017.
<i>Hematology and Pathology Devices Panel of the Medical Devices Advisory Committee</i> —Hematologists (benign and/or malignant hematology), hematopathologists (general and special hematology, coagulation and homeostasis, and hematological oncology), gynecologists with special interests in gynecological oncology, cytopathologists, and molecular pathologists with special interests in development of predictive and prognostic biomarkers.	1	Immediately.
<i>Immunology Devices Panel of the Medical Devices Advisory Committee</i> —Persons with experience in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy, molecular diagnostics, or clinical laboratory medicine.	3	Immediately.
<i>Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee</i> —Experts with cross-cutting scientific, clinical, analytical or mediation skills.	1	Immediately.
<i>Microbiology Devices Panel of the Medical Devices Advisory Committee</i> —Infectious disease clinicians (e.g. pulmonary disease specialists, sexually transmitted disease specialists, pediatric ID specialists, tropical diseases specialists) and clinical microbiologists experienced in emerging infectious diseases; clinical microbiology laboratory directors; molecular biologists with experience in in vitro diagnostic device testing; virologists; hepatologists; or clinical oncologists experienced with tumor resistance and susceptibility.	1	October 1, 2017.
<i>Molecular and Clinical Genetics Devices Panel of the Medical Devices Advisory Committee</i> —Experts in human genetics and in the clinical management of patients with genetic disorders, e.g., pediatricians, obstetricians, neonatologists. Individuals with training in inborn errors of metabolism, biochemical and/or molecular genetics, population genetics, epidemiology and related statistical training, and clinical molecular genetics testing (e.g., genotyping, array CGH, etc.). Individuals with experience in genetics counseling, medical ethics are also desired, and individuals with experience in ancillary fields of study will be considered.	5	Immediately.
<i>Molecular and Clinical Genetics Devices Panel of the Medical Devices Advisory Committee</i> —Experts in human genetics and in the clinical management of patients with genetic disorders, e.g., pediatricians, obstetricians, neonatologists. Individuals with training in inborn errors of metabolism, biochemical and/or molecular genetics, population genetics, epidemiology and related statistical training, and clinical molecular genetics testing (e.g., genotyping, array CGH, etc.). Individuals with experience in genetics counseling, medical ethics are also desired, and individuals with experience in ancillary fields of study will be considered.	2	June 1, 2017.
<i>Neurological Devices Panel of the Medical Devices Advisory Committee</i> —Neurosurgeons (cerebrovascular and pediatric), neurologists (stroke, pediatric, pain management, and movement disorders), interventional neuroradiologists, psychiatrists, and biostatisticians.	4	Immediately.
<i>Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee</i> —Experts in perinatology, embryology, reproductive endocrinology, pediatric gynecology, gynecological oncology, operative hysteroscopy, pelviscopy, electrosurgery, laser surgery, assisted reproductive technologies, contraception, postoperative adhesions, and cervical cancer and cervixcopy; biostatisticians and engineers with experience in obstetrics/gynecology devices; urogynecologists; experts in breast care; experts in gynecology in the older patient; experts in diagnostic (optical) spectroscopy; experts in midwifery; labor and delivery nursing.	1	Immediately.
<i>Ophthalmic Devices Panel of the Medical Devices Advisory Committee</i> —Ophthalmologists specializing in cataract and refractive surgery and vitreo-retinal surgery, in addition to vision scientists, optometrists, and biostatisticians practiced in ophthalmic clinical trials.	3	February 1, 2018.
<i>Ophthalmic Devices Panel of the Medical Devices Advisory Committee</i> —Ophthalmologists specializing in cataract and refractive surgery and vitreo-retinal surgery, in addition to vision scientists, optometrists, and biostatisticians practiced in ophthalmic clinical trials.	1	Immediately.
<i>Ophthalmic Devices Panel of the Medical Devices Advisory Committee</i> —Ophthalmologists specializing in cataract and refractive surgery and vitreo-retinal surgery, in addition to vision scientists, optometrists, and biostatisticians practiced in ophthalmic clinical trials.	2	November 1, 2017.

TABLE 2—EXPERTISE NEEDED, VACANCIES, AND APPROXIMATE DATE NEEDED—Continued

Committee expertise needed	Upcoming vacancies	Approximate date needed
<i>Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee</i> —Orthopaedic surgeons (joint, spine, trauma, and pediatric); rheumatologists; engineers (biomedical, biomaterials, and biomechanical); experts in rehabilitation medicine, sports medicine, and connective tissue engineering; and biostatisticians.	2	September 1, 2017.
<i>Radiological Devices Panel of the Medical Devices Advisory</i> —Physicians with experience in general radiology, mammography, ultrasound, magnetic resonance, computed tomography, other radiological subspecialties and radiation oncology; scientists with experience in diagnostic devices, radiation physics, statistical analysis, digital imaging and image analysis.	1	Immediately.

I. General Description of the Committees Duties

A. Device Good Manufacturing Practice Advisory Committee

The Committee reviews regulations proposed for issuance regarding good manufacturing practices governing the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of devices, and makes recommendations to the Commissioner of Food and Drugs (the Commissioner) regarding the feasibility and reasonableness of those proposed regulations. The committee also advises the Commissioner with regard to any petition submitted by a manufacturer for an exemption or variance from good manufacturing practice regulations that is referred to the committee.

B. Medical Devices Advisory Committee

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The panels engage in a number of activities to fulfill the functions the Federal Food, Drug, and Cosmetic Act (the FD&C Act) envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area performs the following duties: (1) Advises the Commissioner regarding recommended classification or reclassification of devices into one of three regulatory categories, (2) advises on any possible risks to health associated with the use of devices, (3) advises on formulation of product development protocols, (4) reviews premarket approval applications for medical devices, (5) reviews guidelines and guidance documents, (6) recommends exemption of certain devices from the application of portions of the FD&C Act, (7) advises on the necessity to ban a device, and (8) responds to requests from the Agency to review and make recommendations on

specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

The Dental Products Panel also functions at times as a dental drug panel. The functions of the dental drug panel are to evaluate and recommend whether various prescription drug products should be changed to over-the-counter status and to evaluate data and make recommendations concerning the approval of new dental drug products for human use.

The Medical Devices Dispute Resolution Panel provides advice to the Commissioner on complex or contested scientific issues between FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies. The panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory panel proceedings or Agency decisions or actions.

II. Criteria for Voting Members

A. Device Good Manufacturing Practice Advisory Committee

The Committee consists of a core of nine members including the Chair. Members and the Chair are selected by the Secretary of Health and Human Services. Persons nominated for membership as a health professional or officer or employee of any Federal, State, or local government should have knowledge of or expertise in any one or more of the following areas: Quality assurance concerning the design, manufacture, and use of medical

devices. To be eligible for selection as a representative of the general public, nominees should possess appropriate qualifications to understand and contribute to the committee's work. Three of the members shall be officers or employees of any State or local government or of the Federal Government; two shall be representative of the interests of the device manufacturing industry; two shall be representatives of the interests of physicians and other health professionals; and two shall be representatives of the interests of the general public. Almost all non-Federal members of this committee serves as Special Government Employees. Members are invited to serve for overlapping terms of 4 years. The particular needs at this time for this committee are listed in Table 2 of this document.

B. Panels of the Medical Devices Advisory Committee

The Medical Devices Advisory Committee with its 18 panels shall consist of a maximum of 159 standing members. Members are selected by the Commissioner or designee from among authorities in clinical and administrative medicine, engineering, biological and physical sciences, and other related professions. Almost all non-Federal members of this committee serve as Special Government Employees. A maximum of 122 members shall be standing voting members and 37 shall be nonvoting members who serve as representatives of consumer interests and of industry interests. FDA is publishing separate documents announcing the Request for Nominations Notification for Non-Voting Representatives on certain panels of the Medical Devices Advisory Committee. Persons nominated for membership on the panels should have adequately diversified experience appropriate to the work of the panel in such fields as clinical and

administrative medicine, engineering, biological and physical sciences, statistics, and other related professions. The nature of specialized training and experience necessary to qualify the nominee as an expert suitable for appointment may include experience in medical practice, teaching, and/or research relevant to the field of activity of the panel. The particular needs at this time for each panel are listed in table 2 of this document. Members will be invited to serve for terms of up to 4 years.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on one or more of the advisory panels or advisory committees. Self-nominations are also accepted. Nominations must include a current, complete resume or curriculum vitae for each nominee, including current business address and/or home address, telephone number, and email address if available. Nominations must also specify the advisory committee(s) for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: June 20, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-2697]

Submission of Proposed Recommendations for Industry on Developing Continuous Manufacturing of Solid Dosage Drug Products in Pharmaceutical Manufacturing; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: In connection with promoting the use of innovative technologies, the Food and Drug Administration (FDA or Agency) is establishing a public docket to invite discussion of issues related to the adoption of continuous manufacturing by the pharmaceutical industry.

DATES: Submit electronic or written comments by September 21, 2017.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 21, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of September 21, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management

Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-N-2697 for "Submission of Proposed Recommendations for Industry on Developing Continuous Manufacturing of Solid Dosage Drug Products in Pharmaceutical Manufacturing; Establishment of a Public Docket." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.